Chapter 4

Direct-To-Consumer Marketing Campaign: Genetic Testing for Susceptibility to Breast and Ovarian Cancer

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Introduction

Genetic testing
Processes or methods used to analyze human DNA, RNA, genes, chromosomes, proteins, or metabolites in order to detect mutations, chromosomal changes, karyotypes, phenotypes and/or expression pattern variation.

Genetic testing for susceptibility to breast and ovarian cancers is used to search for variants of the ***BRCA1*** and ***BRCA2*** genes that have been associated with cancer in high-risk families. Women who inherit one of these variants have an increased risk of developing breast or ovarian cancer during their lifetime. Most cases of breast and ovarian cancers are not associated with variants in the *BRCA1* or *BRCA2* genes, and the genetic test has not been recommended for routine screening (1,2). *For more information on this topic, see Chapter 5, ACCE Reviews of Genetic Tests: BRCA1, BRCA2, and CFTR.*

BRCA1 and BRCA2
Inherited alterations in the genes, called BRCA1 and BRCA2 (short for Breast Cancer 1 and Breast Cancer 2), are involved in some cases of hereditary breast and ovarian cancers.

The Direct-to-Consumer Marketing Campaign

Despite the limited applicability of the test to the general population, the sole U.S. provider of clinical *BRCA1* and *BRCA2* testing, Myriad Genetic Laboratories, Inc.*, began a pilot **direct-to-consumer marketing (DTC)** campaign in September 2002. The pilot campaign was conducted for 5 months in two cities (Atlanta, Georgia, and Denver, Colorado). The stated intent of the campaign was to raise awareness among women aged 25-54 years with personal or family histories of breast and ovarian cancers; in addition, the campaign was intended to help motivate these women to speak with their health care providers about their personal risk for hereditary breast and ovarian cancers, and to help them find out how a genetic test could help assess and manage their risk (3). Although DTC advertisements for pharmaceuticals have appeared in the mass media for the past 20 years, DTC advertisements for genetic testing have only recently appeared in the mass media and on the Internet (4).

Direct-to-consumer (DTC) marketing
Advertisements that appear in mass media publications, including television and the Internet, which are targeted directly to consumers.

Elements of the campaign included (3):

- *Physician launch mailer,* which was sent to physicians in August 2002 to inform them about the campaign.

- *Television commercial*, which was aired to consumers during prime daytime, early morning, prime access, and early and late fringe from September 2002 to January 2003.

** Use of trade names is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.*

- *Print advertisements*, which appeared from October 2002 to February 2003 in women's magazines, including home, health, entertainment, and regional magazines and newspapers.

- *Red Flags program*, in which materials, including posters, patient brochures, and cancer history tear-off pads for use in medical offices, were mailed to physicians to help patients self-assess their risk for hereditary cancers.

- *Toll-free number and website*, for health care providers and patients to obtain more information.

Public Health Significance

The DTC campaign for genetic testing for inherited breast and ovarian cancer susceptibility is of public health significance for the following reasons:

- Interpretation of the test is complex.

- The test is not appropriate for most women.

- This is the first time an established genetic test has ever been marketed directly to the public through mass media, and it may serve as a prototype for future DTC marketing of genetic tests.

The Complexity of *BRCA1* and *BRCA2* Testing

Results of *BRCA1* and *BRCA2* testing can only be interpreted in the context of family history. An affected person usually must first be tested to determine whether a *BRCA1* or *BRCA2* mutation can be identified within the person's family. Only if a mutation is identified will testing unaffected family members be informative for predicting their cancer risk. Both *BRCA1* and *BRCA2* mutations are not found in all women with family histories of breast or ovarian cancer, and not all women who have a *BRCA1* or *BRCA2* mutation will develop either breast or ovarian cancer (2,5).

BRCA1 and *BRCA2* Tests Are Not Appropriate for Most Women

Most breast and ovarian cancers occur in women who have no family histories of either of these cancers or only a single affected relative. *BRCA1* and *BRCA2* mutations occur in approximately 1 in 400 women and account for, at most, 5%–10% of all cases of breast and ovarian cancers; there are probably other, as yet unidentified, inherited breast cancer susceptibility genes (1,2,5).

Direct-To-Consumer Advertising

DTC advertising of prescription medications and medical tests have proliferated during the past decade. Advocates of DTC advertising argue that it can play an important role in improving the public's health by educating consumers about health conditions and increasing the public's use of appropriate medications and treatments (6). Opponents, however, believe that DTC advertising leads to misconceptions about the health benefits of tests and medicines among consumers (7) and results in the use of more expensive, but not necessarily more effective, drugs and tests (8).

The DTC campaign for breast and ovarian cancer susceptibility marked the first time that an established genetic test was marketed directly to the public, and it may serve as a prototype for future DTC marketing of genetic tests. Because of the complexities surrounding genetic testing, however, it is unclear whether the medical and public health communities are prepared to handle the challenges accompanying an increase in DTC marketing of genetic tests (9).

Public Health Response

An investigation to monitor the impact of the DTC campaign was conducted at the request of state epidemiologists and public health officials in the two pilot cities where the campaign took place (Atlanta, Georgia, and Denver, Colorado) as well as in two control cities (Raleigh-Durham, North Carolina, and Seattle, Washington). The investigation was a joint effort of the four states, the Office of Genomics and Disease Prevention, and the Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Control, Centers for Disease Control and Prevention. Because the campaign was scheduled to end in February 2003, a rapid public health response was required.

Survey Development

Two working groups developed two separate surveys to ask providers and consumers about genetic testing for susceptibility to breast and ovarian cancers.

The consumer survey assessed:

- Awareness about genetic testing for risk of breast and ovarian cancers among women aged 25-54 years in the two cities targeted by the campaign as well as in two cities not targeted by the campaign.
- Self-reported knowledge about this type of genetic testing, by city.
- Respondent characteristics that influence awareness and knowledge of genetic testing for risk of breast and ovarian cancers.

The consumer survey was a programmed telephone survey of randomly selected women aged 25-54 years in four cities. The survey consisted of 51 questions and was conducted between April 21 and May 20, 2003.

The provider survey assessed:

- Physicians' knowledge and awareness about genetic testing for breast and ovarian cancer risk.

- Physicians' perceptions of patient demand for information about this type of genetic testing.

The provider survey, which included 35 questions and a $50 incentive, was mailed to randomly selected physicians in four specialties: family practice, internal medicine, obstetrics/gynecology, and oncology. The initial mailing was conducted on May 1, 2003.

Consumer Survey Results

A total of 1,635 consumer telephone surveys were completed (overall participation rate was 45%; participation rate in Atlanta was 56%; Denver, 42%; Raleigh-Durham, 39%; Seattle, 43%). The average age of respondents was 40 years old. The majority of respondents were white, married, had higher than a 12th-grade education, and had an income greater than $35,000. Overall, 13% of respondents had a first-degree relative with breast or ovarian cancer.

Respondents in the pilot cities were twice as likely as respondents in the control cities to report seeing or hearing an advertisement on television, radio, or in a magazine about a test to determine a woman's risk for breast or ovarian cancer. Self-reported levels of knowledge about genetic testing for breast and ovarian cancers did not differ between the pilot and control cities (Table 1). These findings were similar after stratifying by race, education, and income, although education was positively associated with the self-reported level of knowledge.

Among consumers in all cities, those with a first-degree relative with either breast or ovarian cancer were slightly more likely to recall being exposed to an advertisement about genetic testing for breast or ovarian cancer risk and to report higher levels of knowledge about genetic testing.

Table 1. Consumer Awareness and Knowledge of Genetic Testing for Breast and Ovarian Cancer Susceptibility**

Question	Response Choices	Denver % (N=401)	Atlanta % (N=410)	Raleigh % (N=403)	Seattle % (N=421)
Saw/heard an advertisement about a genetic test to determine a woman's risk for breast or ovarian cancer in the past 6 months[†]	Yes Not yes**	36 (144) 64 (257)	42 (172) 58 (238)	23 (91) 77 (312)	12 (50) 88 (371)
How would you describe your knowledge about genetic testing for breast and ovarian cancer?[§]	Little/nothing Some A lot***	68 (274) 29 (117) 2 (9)	70 (285) 28 (114) 2 (10)	73 (294) 25 (99) 2 (8)	69 (289) 27 (114) 4 (16)

**Some missing values are included.
***Sum of percentages is not always 100 because of "don't know" responses. Missing values are excluded.
[†]χ^2 value = 112.3; P <.001.
[§]χ^2 value = 5.6; P = .47.

Provider Survey Results

In all, 1,054 (66%) provider questionnaires were returned and analyzed. Most respondents were male, had been in practice more than 10 years, and saw fewer than 100 patients per week.

In general, provider knowledge about the inheritance of breast and ovarian cancer risk did not differ between the pilot and control cities (Table 2). The majority responded correctly that a woman with early onset breast cancer was more likely to have inherited a *BRCA1* or *BRCA2* variation than a woman who was affected at a much later age. Oncologists and obstetricians/gynecologists were more likely than family practitioners and internists to know that a *BRCA1* or *BRCA2* variation can be inherited from either parent and that a healthy woman who has a sister with a known *BRCA1* variation has a 50% chance of inheriting the same variation.

Providers in the pilot cities were significantly more likely than providers in the control cities to report having seen or heard, or having patients mention that they had seen or heard, an advertisement promoting genetic testing for breast and ovarian cancer risk in the popular media (Table 2).

Providers were asked to indicate on a 5-point scale how relevant it would be to their practice to learn more about genetic testing for breast and ovarian cancer risk (1 = "not at all relevant" to 5 = "extremely relevant"). The mean rank was 3.5 across all specialties, indicating that most providers felt that gaining this knowledge would be relevant to their practice. Internists were less likely to rank this knowledge as relevant than the other specialties (mean rank = 3.1).

Table 2. Provider Knowledge of Genetic Testing for Breast and Ovarian Cancer Susceptibility and the DTC Campaign by City**

Question	Response Choices	Denver % (N=270)	Atlanta % (N=292)	Raleigh % (N=164)	Seattle % (N=328)
How likely is a woman who gets breast cancer at an early age to have inherited a BRCA1 or BRCA2 variation compared to a woman who gets breast cancer at a much later age?†	More likely	84 (222)	79 (225)	80 (127)	88 (285)
	Equally likely	5 (12)	4 (10)	5 (8)	2 (8)
	Not sure	11 (30)	18 (50)	15 (24)	10 (31)
Women can inherit a BRCA1 or BRCA2 variation from: §	Either parent	55 (146)	52 (147)	43 (68)	52 (171)
	Mother only	12 (31)	17 (47)	21 (34)	16 (53)
	Not sure	33 (87)	31 (88)	36 (57)	32 (103)
What is the chance that a healthy woman who has a 30-year-old sister with a known BRCA1 variation has inherited the same BRCA1 variation?¶	25%	22 (58)	29 (81)	21 (33)	25 (80)
	50%	48 (128)	42 (119)	49 (78)	46 (150)
	75%	3 (8)	2 (5)	2 (3)	1 (4)
	Not sure	27 (70)	27 (77)	28 (45)	28 (89)

Question	Response Choices	Denver % (N=270)	Atlanta % (N=292)	Raleigh % (N=164)	Seattle % (N=328)
Personally saw/ heard an ad about genetic testing for breast/ovarian cancer risk in the past 6 months***	Yes No Not sure	39 (103) 55 (147) 6 (15)	44 (126) 51 (146) 5 (15)	29 (47) 66 (107) 6 (9)	18 (59) 76 (250) 6 (18)
Patients mentioned they had seen/ heard an ad for breast/ ovarian cancer risk in the past 6 months††	Yes No Not sure	28 (74) 68 (178) 4 (11)	27 (78) 67 (191) 6 (17)	10 (16) 87 (140) 3 (5)	8 (26) 99 (286) 4 (12)

**Sum of percentages is not always 100 because of rounding.
† Excludes missing values and five respondents who answered "less likely"; χ^2 value = 12.9; P=.045.
§Excludes missing values and one individual who answered, "father only"; χ^2 value = 9.9; P=.13.
¶Excludes missing values and four individuals who answered "100%"; χ^2 value = 7.8; P=.55.
***χ^2 value = 55.7; P <.0001.
††χ^2 value= 66.8; P <.0001.

Additional findings are reported in a 2004 issue of MMWR (10).

Conclusions

By responding relatively rapidly to the campaign with surveys of consumers and providers, states were able to monitor the campaign's effects on the participants' awareness, knowledge, and perceptions. Findings from this investigation indicate that the DTC campaign for genetic testing for breast and ovarian cancer susceptibility increased awareness about inherited susceptibility to breast and ovarian cancers in the pilot cities. The DTC campaign suggests that women who are interested in learning more about *BRCA1/2* testing should consult their health-care providers. Findings from this study indicate that providers in different specialties are not equally knowledgeable about *BRCA1/2* testing, however, and that many providers are not adequately prepared to respond to their patients' questions about *BRCA1/2* testing. Most providers reported that information about inherited breast and ovarian cancer susceptibility testing would be relevant to their practice. These findings suggest a need for more professional education about genetic testing in general, as well as specifically for inherited susceptibility to breast and ovarian cancer risk.

The Food and Drug Administration (FDA) does not currently regulate most DNA-based tests, including the *BRCA1/2* test (9). Better understanding of the public health impact of DTC marketing of DNA-based tests requires a strategy that includes data collection for the purpose of investigating test utilization and access. Collaboration between public health agencies, clinical care providers, professional organizations, and industry (e.g., biotechnology companies, and laboratories) will be needed to collect these data. Information obtained through these collaborations could serve as a model for future public health responses as genomics becomes more integrated into health care and disease prevention.

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